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| APPLICATION NO.   | FILING DATE                   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-------------------|-------------------------------|----------------------|-------------------------|------------------|
| 10/808,699        | 03/25/2004                    | Marian Nakada        | CEN 5017 USNP           | 5898.            |
| 27777             | 7590 03/30/2006               |                      | EXAM                    | INER             |
| PHILIP S. JOHNSON |                               |                      | HADDAD, MAHER M         |                  |
| JOHNSON &         | JOHNSON<br>ON & JOHNSON PLAZA |                      | ART UNIT .              | PAPER NUMBER     |
|                   | SWICK, NJ 08933-7003          |                      | 1644                    |                  |
|                   |                               |                      | DATE MAILED: 03/30/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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APR 0 3 2006

J&J PAT. DKT. SECTION

|   | ·  | 006 15:51 P.02   |
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| E 40  |  |  |
|   | Application No.  | Applicant(s)   |
| ( 0 5 2006 B  | 10/808,699   | NAKADA ET AL.  |
| Office Action Summary   | Examiner   | Art Unit   |
| A THAPPAN   | Maher M. Haddad  | 1644   |
| The MAILING DATE of this communicatio   | n appears on the cover sheet w   | ith the correspondence address   |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN  Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory is Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). | IG DATE OF THIS COMMUNI FR 1.135(a). In no event, however, may a on. period will apply and will expire SIX (6) MOR statute, cause the application to become A  | CATION. reply be timely filed  ITHS from the mailing date of this communication  BANDONED (35 U.S.C. § 133). |
| Status  |  |  |
| 1) Responsive to communication(s) filed on  |  |  |
|   | This action is non-final.  |  |
| 3) Since this application is in condition for al  |  | ters, prosecution as to the merits   |
| closed in accordance with the practice un   | ider <i>Ex parte Quayle</i> , 1935 C.[   | ). 11, 453 O.G. 213.   |
|   |  |  |
| Disposition of Claims   |  |  |
| 4)⊠ Claim(s) <u>1-18</u> is/are pending in the applic   |  |  |
| 4a) Of the above claim(s) is/are with   | indrawn from consideration.  |  |
| 5) Claim(s) is/are allowed.   |  |  |
| 6) Claim(s) is/are rejected.  |  |  |
| <ul> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) 1-18 are subject to restriction an</li> </ul>   | ad/or election requirement   |  |
| 8) Claim(s) 1-18 are subject to restriction ar  | la/or election requirement.  |  |
| Application Papers  |  |  |
| 9) The specification is objected to by the Example 1.   |  |  |
| 10) The drawing(s) filed on is/are: a)  |  |  |
| Applicant may not request that any objection  |  |  |
| Replacement drawing sheet(s) including the c  | correction is required if the drawing  | (s) is objected to. See 37 CFR 1.121   |
| 11) The oath or declaration is objected to by t   | he Examiner. Note the attache  | d Office Action or form P10-152.   |
| Priority under 35 U.S.C. § 119  |  |  |
| 1'2) Acknowledgment is made of a claim for for a) All b) Some * c) None of:   | reign priority under 35 U.S.C.   | § 119(a)-(d) or (f).   |
| 1. Certified copies of the priority docu  |  |  |
|   | the second to th | Application No.  |
| 2. Certified copies of the priority docu  |  |  |
| <ul><li>2. Certified copies of the priority docu</li><li>3. Copies of the certified copies of the</li></ul>   | e priority documents have beer   |  |
| 2. Certified copies of the priority docu  | e priority documents have beer<br>sureau (PCT Rule 17.2(a)).   | received in this National Stage  |

- 1) Notice of References Cited (PTO-892)
  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

Paper No(s)/Mail Date \_

| ŧ) 🗀 | Interview Summary (PTO-413) |
|------|-----------------------------|
|      | Paper No(s)/Mail Date.      |

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_.

U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05)

Attachment(s)

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## **DETAILED ACTION**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 8-9 and 15-18, drawn to a method for treating an angiogenesis—dependent disease comprising administering to the mammal an EEMMPRIN antagonist and a second anti-angiogenic agent, wherein the angiogenesis-dependent disease is *cancer*, classified in Class 424, subclass 133.1.
  - II. Claims 9-10 and 15-18, drawn to a method for treating an angiogenesis—dependent disease comprising administering to the mammal an EEMMPRIN antagonist and a second anti-angiogenic agent, wherein the angiogenesis-dependent disease is *inflammatory*, classified in Class 424, subclass 133.1.
  - III. Claims 9, 11 and 15-18, drawn to a method for treating an angiogenesis—dependent disease comprising administering to the mammal an EEMMPRIN antagonist and a second anti-angiogenic agent, wherein the angiogenesis-dependent disease is an angiogenic skin, classified in Class 424, subclass 133.1.
  - IV. Claims 9, 12 and 15-18, drawn to a method for treating an angiogenesis—dependent disease comprising administering to the mammal an EEMMPRIN antagonist and a second anti-angiogenic agent, wherein the angiogenesis-dependent disease is a disorder involving corneal or retinal neovascularization, classified in Class 424, subclass 133.1.
  - V. Claims 13-14 and 16-18, drawn to a method for inhibiting tumor growth comprising administering to the mammal an EMMPRIN antagonist and a second anti-angiogenic agent; classified in Class 424, subclass 133.1.

Claims 1-7 link inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1-7. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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2. Groups I -V are different methods. A method of inhibiting and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

## Species Election

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If any one Group I-IV is elected, applicant is required to elect a single specific disease such as those recited in claims 9-11. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

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obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm., A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 14, 2006

Maher Haddad, Ph.D.

Maher Haddad

Patent Examiner

Technology Center 1600